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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,356	07/12/2001	Graham P. Allaway	43966-CB/JPW/SHS	2885

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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/904,356	ALLAWAY ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,28-31 and 33-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26, 28-31, and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

37 C.F.R. § 1.114

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection on 20 May, 2008. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114.

Status of the Claims

Claims 26, 28-31, and 33-35 are pending in the instant application.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 26, 28-31, and 33-35 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The amended claims are directed toward methods of inhibiting fusion between an HIV-1 envelope glycoprotein$^+$ cell (Env$^+$) and a CD4$^+$ cell through the administration of an anti-PM1 monoclonal antibody (Mab) that inhibits HeLa-env$_{JR-FL}$ fusion to a PM1 cell, but not HeLa-env$_{LAI}$ fusion to a PM1 cell. Viruses carrying the JR-FL envelope are commonly referred to as macrophage-tropic isolates or non-syncytium-inducing (NSI) isolates, whereas viruses carrying the Lai envelope are T-cell tropic or syncytium-inducing (SI) viruses. The disclosure provides a fluorescent resonance energy transfer (FRET) assay that is useful for studying membrane fusion events mediated by the HIV-1 envelope. Preliminary evidence suggests that certain β-chemokines (e.g., MIP-1α) may inhibit primary, NSI, Env fusion interactions without inhibiting SI fusion events. However, this interaction appeared to be cell-dependent. Another inhibitory molecule (e.g., OKT4A) was non-specific and inhibited both NSI- and SI-Env mediated events. The disclosure provides a total of four anti-PM1 Mabs designated PA-3, -5, -6, and -7. The disclosure failed to provide any structural guidance pertaining to the amino acid sequence of any of these antibodies. All of these antibodies inhibited both JR-FL and LAI Env fusion-based events, albeit to different extents (see Table 3, p. 61). PA-3, -5, -6, and -7 inhibited JR-FL Env-mediated fusion events 85%, 96%, 92% and 67%, respectively. PA-3, -5, -6, and -7 inhibited Lai Env-mediated fusion events 90%, 100%, 81% and 69%, respectively. Thus, the only disclosed anti-PM1 Mabs were capable of inhibiting both JR-FL and Lai Env-based

fusion events. The amended claims still encompass a large genus of poorly defined monoclonal antibodies.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of anti-PM1 monoclonal antibodies that display preferential inhibitory activities toward NSI (JR-FL)-Env mediated events but not SI (Lai)-Env mediated events.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed.

Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a laundry list disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure form the mere recitation of function and minimal structure is highly unlikely. In the latter case,

disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute

the gen[us]." See *Enzo Biochem*, 323 F.3d at 966, 63 U.S.P.Q.2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 U.S.P.Q.2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358, 69 U.S.P.Q.2d 1274, 1282 (Fed. Cir. 2004). The Federal Circuit has explained that a specification cannot always support expansive claim language and satisfy the requirements of 35 U.S.C. 112 "merely by clearly describing one embodiment of the thing claimed." *LizardTech* v. *Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1346, 76 U.S.P.Q.2d 1731, 1733 (Fed. Cir. 2005).

The issue is whether a person skilled in the art would understand applicant to have invented, and been in possession of, the invention as broadly claimed. See also *Tronzo* v. *Biomet*, 156 F.3d at 1159, 47 U.S.P.Q.2d at 1833 (Fed. Cir. 1998), wherein the disclosure of a species in the parent application did not suffice to provide written description support for the genus in the child application. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements

possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., *Eli Lilly*. If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, paragraph 1. Moreover, the court stated in *University of Rochester* v. *G.D. Searle & Co.*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (Fed. Cir. 2004) that claims directed toward an inhibitory method that fail to set forth a reasonable number of inhibitory agents are appropriately rejected under this section. The facts in this case are similar to the ones in the instant application.

As set forth supra, the disclosure describes the preparation of four anti-PM1 Mabs designated PA-3, -5, -6, and -7. All of these antibodies inhibited **both** JR-FL and LAI Env fusion-based events, albeit to different extents (see Table 3, p. 61). PA-3, -5, -6, and -7 inhibited JR-FL Env-mediated fusion events 85%, 96%, 92% and 67%, respectively. PA-3, -5, -6, and -7 inhibited Lai Env-mediated fusion events 90%, 100%, 81% and 69%, respectively. Thus, the only disclosed anti-PM1 Mabs were capable of inhibiting both JR-FL and Lai Env-based fusion events. The disclosure fails to identify any anti-PM1 Mabs that were capable of inhibiting JR-FL Env-based fusion events, but not Lai Env-based fusion events. The disclosure fails to provide sufficient guidance pertaining to the binding specificity of the anti-PM1 Mabs of interest. Which antigens and epitopes are recognized by these Mabs? Do they bind to a linear or conformational-dependent epitope? Do they bind to a

specific cell-surface antigen, viral antigen, or combination of both viral and cellular antigens? Do the Mabs of interest recognize a transient epitope that is present only during the fusion process? Moreover, the disclosure fails to provide any guidance pertaining to the molecular determinants modulating JR-FL/Lai Env fusion-mediated events. Thus, the skilled artisan is essentially being asked to guess as to which antigens the Mabs of interest might recognize. The disclosure also fails to provide sufficient guidance pertaining to the structure of any given monoclonal antibody. Finally, the lack of a structural/functional correlation fails to lead the skilled artisan to any particular Mab and the disclosure has not provided a reproducible method for obtaining the Mabs of interest. Accordingly, the skilled artisan would reasonably conclude that applicants were **not** in possession of the claimed invention at the time of filing.

Response to Applicants' Arguments

Applicants traverse and submit the claim amendments obviate the rejection. It was argued that the structural characteristics of any given antibody could easily be determined. Additionally, it was argued that the functional limitations also further define the invention. Finally, applicants submit that the specification provides a reasonable number of embodiments. These arguments are not deemed to be persuasive for the reasons of record set forth in the preceding rejection. First, the structural characteristics of any given Mab will vary considerably. Even antibodies that bind to the same antigen display different coding potentials. The complementarity determining regions (CDRs) provide considerable

genotypic/phenotypic diversity to any given antibody. The skilled artisan cannot reasonably predict what sequence any given anti-PM1 Mab will contain. Moreover, contrary to applicants' assertions, the anti-PM1 Mabs set forth in the specification do not display the claimed characteristics (e.g., inhibiting JR-FL, but not, Lai Env-mediated fusion events). As set forth in the preceding rejection, Mabs PA-3, 5, -6, and -7 inhibit both binding events, albeit to different extents. Thus, applicants' arguments are clearly not persuasive.

Enablement

Claims 26, 28-31, and 33-35 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The amended claims are directed toward methods of inhibiting fusion between an HIV-1 envelope glycoprotein^{+} cell (Env^{+}) and a $CD4^{+}$ cell through the administration of an anti-PM1 monoclonal antibody (Mab) that inhibits HeLa-env_{JR-FL} fusion to a PM1 cell, but not HeLa-env_{LAI} fusion to a PM1 cell. Viruses carrying the JR-FL envelope are commonly referred to as macrophage-tropic isolates or non-syncytium-inducing (NSI) isolates, whereas viruses carrying the Lai envelope are T-cell tropic or syncytium-inducing (SI) viruses. The disclosure provides a fluorescent resonance energy transfer (FRET) assay that is useful for studying membrane fusion events mediated by the HIV-1 envelope. The disclosure provides a total of four anti-PM1 Mabs designated PA-3, -5, -6, and -7. The disclosure failed to

provide any structural guidance pertaining to the amino acid sequence of any of these antibodies. All of these antibodies inhibited **both** JR-FL and LAI Env fusion-based events, albeit to different extents (see Table 3, p. 61). PA-3, -5, -6, and -7 inhibited JR-FL Env-mediated fusion events 85%, 96%, 92% and 67%, respectively. PA-3, -5, -6, and -7 inhibited Lai Env-mediated fusion events 90%, 100%, 81% and 69%, respectively. Thus, the only disclosed anti-PM1 Mabs were capable of inhibiting both JR-FL and Lai Env-based fusion events. However, the claims clearly require a Mab that is capable of inhibiting JR-FL Env fusion-based events, but not Lai Env fusion-mediated events.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

1) The disclosure fails to provide adequate guidance pertaining to the structural/functional characteristics of the claimed

genus of antibodies. The disclosure fails to provide any nucleotide/amino acid sequence for any given antibody. The disclosure fails to identify the antigen(s) or epitope(s) of interest. The disclosure fails to provide any guidance pertaining to the functional properties of any given anti-PM1 Mab (i.e., binding affinity; binding avidity; binding specificity; isotype; etc.).

2) The disclosure fails to provide a reproducible method for preparing antibodies with the recited characteristics. The only Mabs disclosed fails to display the claimed characteristics and the specification is silent concerning methods for generating the desired Mabs.

3) The disclosure fails to provide any working embodiments. The claims require an anti-PM1 Mab that is capable of inhibiting JR-FL Env-mediated fusion events, but not Lai Env-mediated fusion events. As previously set forth, the disclosure only provides anti-PM1 Mabs that are capable of inhibiting both JR-FL and Lai Env-mediated fusion events.

4) Antibody development is associated with considerable diversity thereby precluding the ability of the skilled artisan to predict or ascertain the structure of any given antibody beforehand. Accordingly, the skilled artisan can only determine the coding potential of any given antibody after it has been developed.

Accordingly when all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 U.S.P.Q.2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); and *In re Thorington*, 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) or § 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

The previous rejection of claims 26-35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,118,859, is hereby withdrawn in response to applicants' amendment and upon further consideration of the claimed/patented subject matter. Applicants are reminded that they are required to maintain a clear line of demarcation between different inventions/applications. The patented subject matter in the '859 patent should be carefully considered when drafting future claim language.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin, Ph.D./
Primary Examiner, Art Unit 1648

18 August, 2008